 <b>Independent Verification &amp; Validation Facility</b>	<b>Corrective and Preventive Action</b>	<b>IVV 14 Revision: K Effective Date: April 28, 2004</b>
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<b>APPROVAL SIGNATURES</b>		<b>DATE</b>
Greg Blaney (original signature on file)	Management System Representative	04/27/2004

<b>REVISION HISTORY</b>			
Rev No.	Description of Change	Author	Effective Date
Basic	Initial Release	John Griggs IT/204	05/01/98
A	Section 2.0,3.0,5.0 And 6.0 were modified and added flow chart.	Siamak Yassini IT/332	07/23/98
B	Quality Record - format change, modified section 2.2	Siamak Yassini IT/332	08/26/98
C	Consolidated forms	Siamak Yassini IT/332	01/28/99
D	References to Ames Quality Manual replaced with references to IV&V Facility Quality Manual Updated Section 5.1.4 & 6.1.2	Siamak Yassini IT/332	09/10/99
E	Adding Track wise automated tool section 3.3	Siamak Yassini IT/332	03/30/00
F	Format and Number changes; Delete Reference to Ames Research Center	Griggs	12/06/00
G	Significant re-write to accommodate current process	Griggs	04/03/01
H	Revise severity codes to define "immediate", also require corrective action plans	Griggs	09/13/01
I	Revise to include lower tier action tracking systems, and to modify the automated flow to allow staff to enter CAR/PARs	Griggs	06/06/02


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REVISION HISTORY (CONTINUED)			
Rev No.	Description of Change	Author	Effective Date
J	Clarify initial assignment of CAR/PAR to Management Representative; also clarify use of IVV Form 1005 as backup to Trackwise	Griggs	10/21/02
K	Updated process flow to current flow practices; verbiage updated to meet new acronym and system references (IMS)	Kesecker	04/28/2004

REFERENCE DOCUMENTS	
Document Number	Document Title
IVV QM	IV&V Facility Quality Manual
IVV 16	Control of Quality Records
IVV 17	Internal Quality Audits

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## 1.0 Purpose

The purpose of this System Level Procedure (SLP) is to define the corrective and preventive action processes at the NASA IV&V Facility that tracks the identification and resolution of product and service nonconformances and customer complaints.

The processes include the formal C/PAR tracking system, and three lower-tier action tracking systems that support internal objectives.

## 2.0 Scope

This procedure applies to all processes, products, and services found nonconforming or potentially nonconforming pursuant to the IV&V Facility's Management System (IMS).

## 3.0 Definitions and Acronyms

### 3.1 Nonconformance


A “nonconformance” is defined as a lack of compliance to a specified process or procedure associated with the IMS, a nonconforming product, or a deficiency in the IMS itself. For the purposes of this procedure, nonconformances will be categorized into three levels of severity.

**Major** - a system deficiency exists; a nonconforming product is issued and the nonconformity has a significant effect on customer success, safety, or resources; lack of documented procedures, documented procedures are not being implemented consistently, or a series of minor nonconformities indicated an overall system weakness which has an adverse effect upon overall product.

**Minor** - a defined system exists with an acceptable level of implementation, however, there are minor discrepancies or lapses in discipline; a nonconforming product is issued and the nonconformity has little or no effect on the customer.

**Observation** - an issue noted by an auditor that may lead to a non-conformity if not corrected, a suggestion to improve a process, or editorial corrections to a procedure (i.e. typing errors, misspelling, etc.).

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### **3.2 Corrective Action (CA)**

Action taken to eliminate the cause(s) of an existing nonconformity, defect or other undesirable situation with a product or process in order to prevent recurrence.

### **3.3 Preventive Action (PA)**

Actions determined from recognition of issues which could lead to nonconformities, or the analysis of data to detect trends and identify causes that may result in future nonconformances.

### **3.4 Corrective/Preventive Action Request (C/PAR)**

A C/PAR is the documentation of a nonconformance or potential nonconformance. C/PARs can result from multiple activities or come from multiple sources (i.e. internal or external audits, actions from management's review of the IMS, customer complaints, etc.).

### **3.5 TrackWise**

Action tracking system utilized by the IV&V Facility to capture, track, and report on C/PARs.

### **3.6 Product**

A product is the result of activities or processes, which may include service, software, analysis reports, or a combination of these.


### **3.7 Corrective and Preventive Action (C&PA) Manager**

The individual designated by Facility Management who is responsible for managing the corrective and preventive action system.

### **3.8 IV&V Facility Management Representative**

Member of the Facility Management team assigned to oversee the operation of the IMS to a) ensure that processes needed are established, implemented, and maintained, b) report to Facility Management on the performance of the

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IMS and needs for improvement, and c) ensures promotion of awareness of customer requirements throughout the organization.

### **3.9 Assignee**

The person assigned action for a C/PAR by the Management Representative.

### **3.10 Initiator**

Individual staff member/contractor working within the IMS, noting need for change or improvement.

### **3.11 Lower-Tier Action Tracking**


Administrative, Project Management, and Research Management action tracking systems not requiring Facility-wide access are used for internal process tracking of actions, including delivery dates, etc. These systems support the C/PAR system, and significant issues are upgraded into the C/PAR system. Procedures for these systems reside with the owner.

The Administrative action tracking system is controlled by the Director's Office, and tracks administrative actions.

The Project Manager's action tracking system is internal to the Project Management structure, tracking actions from the Project Manager's meetings. In the Project Manager's meetings, notes are taken and stored on the Facility's shared drive. Recorded in those notes are Action Items (AI) assigned during these meetings. Often the AIs generated are simple, one-time items which are taken care of and closed. AIs from previous meetings are reviewed and if not completed, are recorded once again in the meeting minutes, appearing weekly until the action is closed. If an AI is deemed to be systemic to the Facility or can affect the quality of the Facility's products, it will be recorded in the C/PAR system rather than as an AI.

The Research Management group maintains an informal action item tracking database within the Center Initiative Management (CIM) Tool. The primary purpose of this database is to track the progress of day-to-day assignments and actions. In that context, it supplements the C/PAR system. Items of significance to the entire Facility staff must still be entered into the C/PAR system.

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#### 4.0 Flowchart

The process flow for Corrective and Preventive Action is depicted in the flowchart on the next page. The TrackWise flow describes the responsible persons and actions for each step of the corrective and preventive action tracking process, from origination through closure.

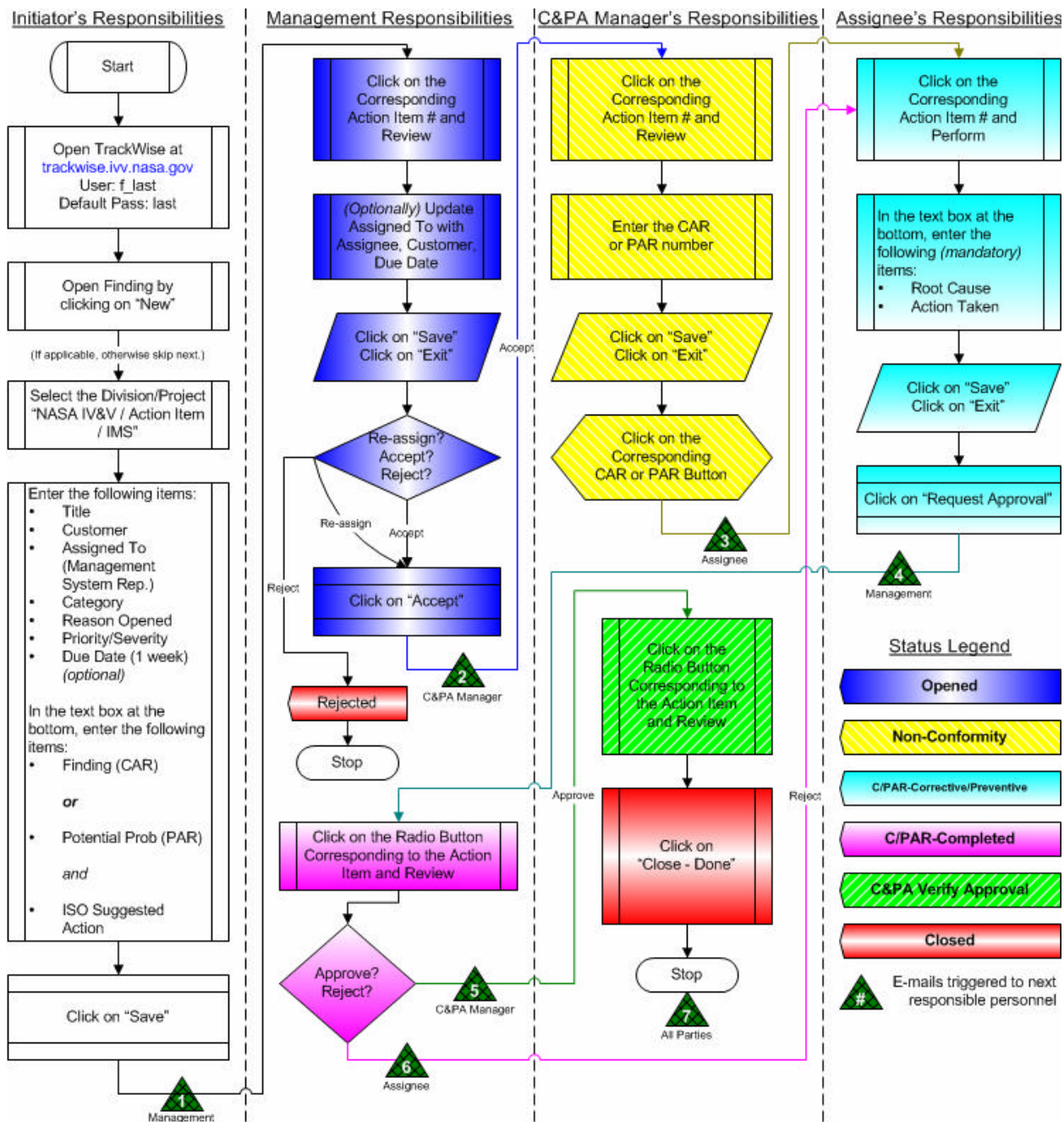


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**4.1 TrackWise Process Flowchart**



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## 5.0 Responsibilities

### 5.1 Management System Representative

The Management Representative is responsible for the following:

- Ensure the corrective and preventive action process is established, administered, and utilized to maintain IMS process improvement.
- Ensure C/PARs are assigned to appropriate personnel with due dates identified.
- Ensure timely responses to C/PARs by assigned personnel.

### 5.2 Corrective and Preventive Action (C&PA) Manager

The C&PA Manager is responsible for the following:

- Establishing and maintaining a system for corrective and preventive action.
- Administering control of the C/PAR process.
- Resolving conflicts and/or misunderstandings of required actions.
- Preparing the Corrective and Preventive Action Management Status Report.

### 5.3 All Personnel

Any IV&V Facility employee subject to the scope of the IMS is responsible for entering a C/PAR if a nonconformance or a potential nonconformance is observed within the IMS.


### 5.4 The Assignee

The Assignee is responsible for the following actions when a C/PAR is submitted and assigned to them by the Management Representative.

- Determine and document the root cause(s) of the nonconformance.
- Identify, document, and implement required changes to address the C/PAR.
- Ensure that all applicable data, including incorporated changes to operating practices, are documented.
- Submit responses in a timely manner to the C&PA Manager.
  - A CAR with a severity of Minor or Observation, which is expected to require over 30 days to resolve and implement requires a Corrective Action Plan to be submitted and approved

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- by the Management Representative within 30 days of assignment, and filed within the C/PAR system
- A CAR with severity of Major requires completed corrective action or an approved corrective action plan within 2 weeks.
- A PAR will be assigned an appropriate due date by the Management Representative when assigned.
- Request line management support when required for timely response and closure.

## 6.0 Procedure

A C/PAR is originated whenever a current or potential nonconformity warrants a root cause analysis and corrective or preventive action because the nonconformity has or may have an effect on the quality of the products or services the IV&V Facility produces.


### 6.1 Originate a Corrective or Preventive Action

Any employee subject to the IMS observing a nonconformance or potential nonconformance shall initiate a corrective or preventive action.

- The identifier/originator of the nonconformance shall initiate a C/PAR by entering the following required information (except where noted) into the TrackWise system:
  - Title
  - Customer
  - Assigned To (Management System Representative)
  - Category
  - Reason Opened
  - Priority/Severity
  - Due Date (1 week) (optional)
- The identifier/originator shall then save the C/PAR into the system; the system will notify the Management Representative for evaluation and assignment. *(Note: using the Save+ button performs the same function as the Save button, but leaves the system open ready to enter another C/PAR.)*

*NOTE: Form IVV 1005, Finding Report, may be used to initiate a CAR or PAR if TrackWise is not available. In that case, forward the completed form to the C&PA Manager for action.*

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## 6.2 C/PAR Evaluation and Assignment

Based upon the data submitted, the Management Representative shall either accept the C/PAR and designate an Assignee for the investigation and resolution action or close the C/PAR because it is not a nonconformance.

- If the C/PAR is valid, the Management Representative shall designate an Assignee for the investigation and resolution action with an associated due date and indicate acceptance in TrackWise. The TrackWise system will then notify the C&PA Manager that an accepted C/PAR needs to be processed.
- If the C/PAR is determined to be invalid, the Management Representative shall indicate rejection in TrackWise. This will close the C/PAR and no further action is required.

## 6.3 Logging and Tracking of C/PAR


The C&PA Manager will perform the following actions upon notification of an accepted C/PAR:

- Assign a C/PAR number.
- Indicate whether it is a corrective or preventive action.
- Save the C/PAR in TrackWise.

## 6.4 Processing of C/PAR

The Assignee shall perform the following actions upon notification of an assigned C/PAR action.

- Investigate, document, and implement the required corrective and/or preventive actions in the IMS processes or procedures.
- Enter Root Cause information into TrackWise.
- Enter Action Taken information into TrackWise.
- Enter, optionally, Objective Evidence showing resolution of nonconformity into TrackWise.
- Save the C/PAR in TrackWise.
- Click on "Request Approval" in TrackWise. This will submit the completed C/PAR to the Management Representative for acceptance or rejection of the resolution implemented by the Assignee.

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## 6.5 Management Review of C/PAR Resolution

The Management Representative shall determine if the resolution actions taken by the Assignee are acceptable to eliminate or preclude the nonconformance identified in the C/PAR.

### 6.5.1 Acceptable C/PAR Resolution

If the Assignee's actions taken in response to the C/PAR are adequate and acceptable to the Management Representative, the Management Representative will approve the resolution in TrackWise. This will cause the system to submit the C/PAR to the C&PA Manager for closure.


### 6.5.2 Unacceptable C/PAR Resolution

If the Assignee's actions taken in response to the C/PAR are not adequate or acceptable, the C/PAR will be rejected and returned to the Assignee to work again. The Assignee must again go through the request for approval process after re-working the C/PAR.

## 7.0 Metrics

The C&PA Manager shall report metrics to the Management Representative at the Quarterly Management Review (QMR). Such metrics may include the following:

- Total number of C/PARs open
- Number of C/PARs opened during reporting period
- Number of C/PARs closed during reporting period
- Number of open C/PARs where no action was taken during reporting period
- Age of all open C/PARs

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## 8.0 Records

The following records will be generated per this procedure and will be managed in accordance with IVV 16, Control of Quality Records.

Document Name and Identification Number	User Responsible for Record Retention	Retention Requirement	Location
C/PAR Database from TrackWise tool (or IVV Form 1005)	C/PAR Manager	5 years	C/PAR Manager Folder

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